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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,812

10/11/2005

Guido F. Smoorenburg

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09/09/2009

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EXAMINER

HOLMES, REX R

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

09/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,812	SMOORENBURG, GUIDO F.	
	Examiner	Art Unit	
	REX HOLMES	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/23/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/23/09 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3-4 and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 3 and 4 recite the limitation "the ECAP thresholds" in line 3. There is insufficient antecedent basis for this limitation in the claim.

5. Claims 23 and 24 recite the limitation "the ECAP thresholds" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4, 7-14, 20-24, 27-34 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys et al. (U.S. Pat. 6,157,861 hereinafter "Faltys 861") in view of Faltys et al. (U.S. Pat. 6,289,247 hereinafter "Faltys 247").
3. Regarding claims 1-4, 20-22 and 38, Faltys 861 discloses a method for fitting a cochlear implant with multiple channels that includes establishing an initial current using action potentials, and then adjusting the levels to conform to the comfort levels of the patient (e.g. Abstract, Figs. 3A-3B, Cols. 3-4). Faltys 861 further discloses that the stimulator can be connected to a clinicians computer for direct interface between the clinician and the speech processor (e.g. Col. 7, 48-65; Col. 9, line 65 to Col. 10, line 7).
4. Regarding claims 7-14 and 27-34, Faltys 861 discloses adjusting the initial parameters to conform to patient comfort levels by adding or subtracting current levels, thereby effectively shifting tilting or curving the levels of the parameters (e.g. Col. 13, lines 32 to Col. 14 line 53).
5. Regarding claim 23-24, Faltys 861 discloses that the initial current level is established based on the measured action potentials (e.g. Col. 11, ll. 38-48).
6. Regarding claims 1-4, 7-14, 20-24, 27-34 and 38, Faltys 861 discloses the claimed invention but fails to disclose obtaining a response for a plurality of channels and adjust the current level setting for a plurality of channels. However, Faltys 247 discloses a multi-channel stimulator that establishes a speech strategy that is comprised of the polarity, magnitude, location (which electrode pair receives the stimulation current), and timing (when the stimulation current is applied to the electrode

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pair) of the stimulation current that is generated by the ICS (Col. 9, ll. 51-54). It then takes the speech processing strategy which contains the stimulation information for each channel in the array and supplies stimulation to the array based on the values of the initial stimulation strategy, it then receives a feedback signal in response to the initial stimulation, it then adjusts the stimulation channels until the patient senses audio signals correctly (Col. 4, ll. 14-36; Col. 21, line 33 to Col. 22, line 29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the individual adjustment system as taught by Faltys 861, with the combined sensing and adjusting of the parameters for a plurality of channels as taught by Faltys 247, since such a modification would provide the predictable results of optimizing, automating and accurately setting the implant parameters without the need for patient feedback.

7. It is noted that the claim does not state that the stimulation has to be a single signal, that the response has to be a single signal or that the plurality of current level setting have to be adjusted simultaneously. Therefore the speech processor strategy of Faltys 247 encompasses the claimed subject matter as the original speech processing strategy (which contains stimulation specs for every channel in the array, including current levels) is applied, it obtains a feedback response, and then it adjusts the channels of the strategy based on the obtained response.

8. Regarding claims 15-19 and 35-37, Faltys 861 in view of Faltys 247 disclose that it uses known signals to test and fit the cochlear input, but fails to explicitly state that the signals are live speech, an artificial signal or a recorded signal. It would have been

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obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Faltys 861, with a live speech signal, an artificial signal or a recorded signal since it was known in the art that any of a number of signals can be used to create a stimulation signal to produce a response. A live speech signal, artificial signal or a recorded signal all known in the art and using them would provide the predictable result of creating an action potential to monitor and be analyzed.

9. Regarding claims 5-6 and 25-26, Faltys 861 in view of Faltys 247 disclose the claimed invention including that the current levels are set to a default level, but fails to explicitly state that the default levels were based on values that were researched and worked for a vast majority of recipients. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the initial current level as taught by Faltys 861, with an initial current level that was analyzed from a vast majority of people since it was known in the art that the default level should be one that works as a base line for a vast majority of people and using one that works as a base line for a vast majority of people would provide the predictable result of allowing the clinician to quickly fit a cochlear implant as the values would be approximately the right value from the start.

Response to Arguments

10. Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762